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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,310	08/25/2000	Paul B. Fisher	62943/JPW/JML	6406

7590 07/13/2005

Lisa B. Kole
Baker Botts L.L.P.
30 Rockefeller Plaza
New York, NY 10112

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/648,310	FISHER ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,56,58,64,70,72,74 and 80* is/are rejected.

7)☒ Claim(s) *55,57,59-63,65-69,71,73,75-79 and 81-85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

Applicant's submission (amendment and declaration) filed on 04/20/2005 is acknowledged.

Claims 54-85 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 58-69, and 74-85 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell for protein expression purposes, does not reasonably provide enablement for host cell in gene therapy or any other in vivo use is withdrawn because applicant argument is persuasive in light of Dr. Fisher's Declaration.

Allowable Subject Matter

The indicated allowability of claims 54-57, and 70-73 is withdrawn in view of the art rejection below.

The Following are New Grounds of Rejections

Claim Rejections - 35 USC § 102

Claims 54, 56, 58, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number AA891725 (a copy provided on 1/30/2003, 08-JAN-1999). This is reinstatement of the art rejection in the Office action mailed on 1/30/2003.

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 2 (claim 54), vector containing said nucleic acid (claim 56), a host cell containing said nucleic acid (claim 58), host cell containing said vector (claim 64).

Applicant argued that the prior art of record is an EST sequence, and there is no teaching of operatively linking an enhancer element to the EST.

These arguments have been fully considered. However, the Office reinstates the rejection because the isolated nucleic acid disclosed in GenBank accession number AA891725 comprises a nucleic acid encoding SEQ ID NO: 2 as claimed in the instant claim 54. GenBank accession number AA891725 also discloses that the nucleic acid is in a pT7T3Pac between the EcorR1 and NotI. Bonaldo et al (1996, Genome Research, vol. 6, pages 791-806) are cited to present an evidence that the nucleic acid of the prior art is operatively linked to a promoter. Bonaldo et al., at Figure 6 at page 802 disclose that pT7T3Pac that the prior art nucleic acid is inserted in inherently has T7 promoter and the EcorR1 and Not I is in the polylinker region flanked by T7 and T3 promoter. Therefore it is the Office position that the nucleic acid insert is operatively linked to a promoter. In addition, GenBank accession number AA891725 discloses the nucleic acid of GenBank accession number AA891725 is from clone RKIAG02. Voet et al.,(1990, Biochemistry, John Wiley & Sons, page 837) are cited to demonstrate the term "clone" inherently include a host cell, i.e. an organism that contains the vector containing the nucleic acid of interest.

Claims 70, 72, 74, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number N39717 (22-JAN-1996).

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 4 (claim 70), vector containing said nucleic acid (claim 72), a host cell containing said nucleic acid (claim 74), host cell containing said vector (claim 64), and host cell containing vector of claim 72 (claim 80).

GenBank accession number N39717 discloses an isolated nucleic acid comprising a nucleic acid encoding instant SEQ ID NO:4. Note the attached Exhibit A (a sequence alignment of the nucleic acid encoding the instant SEQ ID NO:4 against the nucleic acid disclosed in GenBank accession number N39717) showing the nucleic acid of GenBank accession number N39717 inherently encodes the entire instant SEQ ID NO:4, i.e. 100 % identical. The EST insert encoding the instant SEQ ID NO:4 is in pT7T3Pac, which is designed to put a cDNA insert operatively to a promoter. Note Bonaldo et al (cited above). As for host cell, the vector containing the cDNA insert is in a ampicillin resistant DH10B.

Conclusion

The claims depend on the rejected base claims are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D
Examiner
Art Unit 1642

Exhibit 1
Page 10 of 2

```
  AUTHORS   Kim,N.S., Hahn,Y., Oh,J.H., Lee,J.Y., Ahn,H.Y., Chu,M.Y., Kim,M.R.,
            Oh,K.J., Cheong,J.E., Sohn,H.Y., Kim,J.M., Park,H.S., Kim,S. and
            Kim,Y.S.
  TITLE     21C Frontier Korean EST Project 2001
  JOURNAL   Unpublished (2002)
COMMENT     Contact: Kim YS
            Genome Research Center
            Korea Research Institute of Bioscience & Biotechnology
            52 Eoeun-dong Yuseong-gu, Daejeon 305-333, South Korea
            Tel: +82-42-860-4470
            Fax: +82-42-860-4409
            Email: yongsung@mail.kribb.re.kr
            Plate: 30  row: F  column: 01
            High quality sequence stop: 477.
FEATURES             Location/Qualifiers
     source          1. .477
                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="S3SNU16-30-P01"
                     /sex="F"
                     /tissue_type="Ascites"
                     /cell_type="Lymphoblast-like"
                     /cell_line="SNU-16"
                     /lab_host="Top10F'"
                     /clone_lib="S3SNU16"
                     /note="Organ: Stomach; Vector: pTZ18RP1; Site_1: EcoRI;
                     Site_2: NotI; The poly (A)+ RNA was dephosphorylated with
                     bacterial alkaline phosphatase (BAP) and then decapped
                     with tabacco acid pyrophosphatase (TAP). The decapped
                     intact mRNA was ligated with DNA-RNA linker including EcoR
                     I site by treatment of T4 RNA ligase and the first strand
                     cDNA was synthesized from oligo dT-selected mRNA by
                     priming with dT-tailed vector. The dT-tailed vector was
                     adjusted to have about 60nt. The cDNA vector was
                     circularized with E. coli DNA ligase after digestion of
                     EcoRI which site is also included in vector. An RNA strand
                     converted to a DNA strand by Okayama-Berg method. The
                     obtained cDNA vectors were used for transformation of
                     competent cells E. coli Top10F' by electroporation method.
                     The cDNA libraries constructed by this method are
                     full-length enriched cDNA library."
ORIGIN

Alignment Scores:
Pred. No.:                2.55e-45        Length:         477
Score:                    410.00          Matches:        81
Percent Similarity:       100.00%         Conservative:   0
Best Local Similarity:    100.00%         Mismatches:     0
Query Match:              100.00%         Indels:         0
DB:                       12              Gaps:           0

US-09-648-310-4 (1-81) x BM752941 (1-477)

Qy          1 MetAsnValAspHisGluValAsnLeuLeuValGluGluIleHisArgLeuGlySerLys 20
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        139 ATGAATGTGGATCACGAGGTTAACCTCTTAGTGGAGGAAATTCATCGTTTGGGTTCAAAA 198

Qy         21 AsnAlaAspGlyLysLeuSerValLysPheGlyValLeuPheArgAspAspLysCysAla 40
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        199 AATGCTGATGGAAAGTTAAGCGTGAAATTTGGGGTCCTCTTCCGTGATGATAAATGTGCC 258

Qy         41 AsnLeuPheGluAlaLeuValGlyThrLeuLysAlaAlaLysArgArgLysIleValThr 60
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        259 AACCTCTTTGAAGCATTGGTAGGAACTCTTAAAGCTGCAAAACGAAGGAAGATTGTAACA 318

Qy         61 TyrProGlyGluLeuLeuLeuGlnGlyValHisAspAspValAspIleIleLeuLeuGln 80
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        319 TATCCAGGAGAGCTGCTTCTGCAAGGTGTTCATGATGATGTTGACATTATATTACTGCAA 378

Qy         81 Asp 81
              |||
Db        379 GAT 381
```

```
RESULT 2
BU199007
LOCUS       BU199007                480 bp    mRNA    linear   EST 05-SEP-2002
DEFINITION  DCBCYC05 DCB Homo sapiens cDNA, mRNA sequence.
ACCESSION   BU199007
VERSION     BU199007.1  GI:22717475
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 480)
  AUTHORS   Xu,X., Gu,J., Liu,F., Qu,J., Zhao,M., Li,Y., Huang,Q., Zhou,J.,
            Song,H., Gu,Y., Yang,Y., Gao,G., Xiao,H., Li,N., Qian,B., Gao,X.,
            Cheng,Z., Xu,S., Gu,W., Tu,Y., Jia,J., Fu,G., Ren,S., Zhong,M.,
            Lu,G., Cheng,Z. and Han,Z.
  TITLE     Homo sapiens cDNA DCB clones
  JOURNAL   Unpublished (2000)
COMMENT     Contact: Zeguang Han
            Chinese National Human Genome Center at Shanghai
            351 Guo Shoujing Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai
            201203, P. R. China
            Tel: 86-21-50801919(ex.45)
            Fax: 86-21-50801922
            Email: hanzg@chgc.sh.cn.
FEATURES             Location/Qualifiers
     source          1. .480
                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /cell_type="dendritic cells"
                     /dev_stage="mature"
                     /lab_host="BM25.8"
                     /clone_lib="DCB"
                     /note="Vector: pTriplEx2; Site_1: sfiIA; Site_2: sfiIB"
ORIGIN

Alignment Scores:
Pred. No.:                2.58e-45        Length:         480
Score:                    410.00          Matches:        81
Percent Similarity:       100.00%         Conservative:   0
Best Local Similarity:    100.00%         Mismatches:     0
Query Match:              100.00%         Indels:         0
DB:                       13              Gaps:           0

US-09-648-310-4 (1-81) x BU199007 (1-480)

Qy          1 MetAsnValAspHisGluValAsnLeuLeuValGluGluIleHisArgLeuGlySerLys 20
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        189 ATGAATGTGGATCACGAGGTTAACCTCTTAGTGGAGGAAATTCATCGTTTGGGTTCAAAA 248

Qy         21 AsnAlaAspGlyLysLeuSerValLysPheGlyValLeuPheArgAspAspLysCysAla 40
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        249 AATGCTGATGGAAAGTTAAGCGTGAAATTTGGGGTCCTCTTCCGTGATGATAAATGTGCC 308

Qy         41 AsnLeuPheGluAlaLeuValGlyThrLeuLysAlaAlaLysArgArgLysIleValThr 60
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        309 AACCTCTTTGAAGCATTGGTAGGAACTCTTAAAGCTGCAAAACGAAGGAAGATTGTAACA 368

Qy         61 TyrProGlyGluLeuLeuLeuGlnGlyValHisAspAspValAspIleIleLeuLeuGln 80
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        369 TATCCAGGAGAGCTGCTTCTGCAAGGTGTTCATGATGATGTTGACATTATATTACTGCAA 428

Qy         81 Asp 81
              |||
Db        429 GAT 431
```

```
RESULT 3
N39717
LOCUS       N39717                  532 bp    mRNA    linear   EST 22-JAN-1996
DEFINITION  yx92d07.r1 Soares melanocyte 2NbHM Homo sapiens cDNA clone
            IMAGE:269197 5', mRNA sequence.
```

CESSION N39717
RSION N39717.1 GI:1163262
YWORDS EST.
URCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
FERENCE 1 (bases 1 to 532)
AUTHORS Hillier,L., Clark,N., Dubuque,T., Elliston,K., Hawkins,M., Holman,M., Hultman,M., Kucaba,T., Le,M., Lennon,G., Marra,M., Parsons,J., Rifkin,L., Rohlfing,T., Soares,M., Tan,F., Trevaskis,E., Waterston,R., Williamson,A., Wohldmann,P. and Wilson,R.
TITLE The WashU-Merck EST Project
JOURNAL Unpublished (1995)
MMENT Contact: Wilson RK
Washington University School of Medicine
4444 Forest Park Parkway, Box 8501, St. Louis, MO 63108
Tel: 314 286 1800
Fax: 314 286 1810
Email: est@watson.wustl.edu
High quality sequence stops: 414
Source: IMAGE Consortium, LLNL
This clone is available royalty-free through LLNL ; contact the IMAGE Consortium (info@image.llnl.gov) for further information.
Seq primer: T7
High quality sequence stop: 414.

ATURES Location/Qualifiers
source 1. .532
/organism="Homo sapiens"
/mol_type="mRNA"
/db_xref="GDB:3878839"
/db_xref="taxon:9606"
/clone="IMAGE:269197"
/sex="Male"
/tissue_type="melanocyte"
/lab_host="DH10B (ampicillin resistant)"
/clone_lib="Soares melanocyte 2NbHM"
/note="Vector: pT7T3D (Pharmacia) with a modified polylinker; Site_1: Not I; Site_2: Eco RI; 1st strand cDNA was primed with a Not I - oligo(dT) primer [5' TGTTACCAATCTGAAGTGGGAGCGGCCGCAGTTTTTTTTTTTTTTTT 3'], double-stranded cDNA was size selected, ligated to Eco RI adapters (Pharmacia), digested with Not I and cloned into the Not I and Eco RI sites of a modified pT7T3 vector (Pharmacia). Library constructed by Bento Soares and M.Fatima Bonaldo. RNA from normal foreskin melanocytes (FS374) was kindly provided by Dr. Anthony P. Albino."

RIGIN

lignment Scores:

red. No.:	2.96e-45	Length:	532
core:	410.00	Matches:	81
ercent Similarity:	100.00%	Conservative:	0
est Local Similarity:	100.00%	Mismatches:	0
uery Match:	100.00%	Indels:	0
B:	14	Gaps:	0

S-09-648-310-4 (1-81) x N39717 (1-532)

```
y          1 MetAsnValAspHisGluValAsnLeuLeuValGluGluIleHisArgLeuGlySerLys 20
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
b         90 ATGAATGTGGATCACGAGGTTAACCTCTTAGTGGAGGAAATTCATCGTTTGGGTTCAAAA 149

y         21 AsnAlaAspGlyLysLeuSerValLysPheGlyValLeuPheArgAspAspLysCysAla 40
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
b        150 AATGCTGATGGAAAGTTAAGCGTGAAATTTGGGGTCCTCTTCCGTGATGATAAATGTGCC 209

y         41 AsnLeuPheGluAlaLeuValGlyThrLeuLysAlaAlaLysArgArgLysIleValThr 60
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
b        210 AACCTCTTTGAAGCATTGGTAGGAACTCTTAAAGCTGCAAAACGAAGGAAGATTGTAACA 269

y         61 TyrProGlyGluLeuLeuGlnGlyValHisAspAspValAspIleIleLeuLeuGln 80
```

```
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       270 TATCCAGGAGAGCTGCTTCTGCAAGGTGTTCATGATGATGTTGACATTATATTACTGCAA 329

Qy        81 Asp 81
             |||
Db       330 GAT 332
```

RESULT 4
BG944932
LOCUS BG944932 542 bp mRNA linear EST 15-JAN-2003
DEFINITION ax56e07.x1 Hembase; Erythroid Progenitor Cells (LCB:ax library) Homo sapiens cDNA clone ax56e07 random, mRNA sequence.
ACCESSION BG944932
VERSION BG944932.1 GI:14344293
KEYWORDS EST.
SOURCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 542)
AUTHORS Gubin,A.N., Njoroge,J.M., Bouffard,G.G. and Miller,J.L.
TITLE Gene expression in proliferating human erythroid cells
JOURNAL Genomics 59 (2), 168-177 (1999)
MEDLINE 99339981
PUBMED 10409428
COMMENT Contact: Jeffery L. Miller
Laboratory of Chemical Biology
National Institute of Diabetes and Digestive and Kidney Diseases
Building 10, Room 9B17, National Institutes of Health, Bethesda, MD 20892, USA
Tel: 301 402 2373
Fax: 301 435 5148
Email: jm7f@nih.gov
DNA Sequencing and analyses by National Institutes of Health Intramural Sequencing Center (NISC).
Plate: 56 row: e column: 07
Seq primer: -21M13 forward primer (ABI).

FRATURES Location/Qualifiers
source 1. .542
/organism="Homo sapiens"
/mol_type="mRNA"
/db_xref="taxon:9606"
/clone="ax56e07"
/sex="unknown"
/tissue_type="blood"
/cell_type="Erythroid Cells"
/cell_line="Primary Culture of Peripheral Blood Mononuclear Cells"
/dev_stage="Progenitor; EPO responsive CD71++++"
/lab_host="SOLR"
/clone_lib="Hembase; Erythroid Progenitor Cells (LCB:ax library)"
/note="Organ: blood; Vector: Lambda ZAP II; Site_1: EcoRI; Site_2: EcoRI; 65,000 proliferating erythroid cells from the buffy coat of a blood donation were obtained by flow cytometric separation after a 5-day culture period in the presence of erythropoietin. Total RNA was purified from the sorted cell population using TRIzol reagent. RNA (0.3 ug) was converted into double stranded cDNA using Clontech's CapFinder cDNA Library Construction Kit (Clontech) according to the manufacturer's protocol and cloned into EcoRI digested Lambda Zap II vector (Stratagene). The phage library was amplified once prior to in vivo excision in SOLR cells. Individual colonies were grown, and the cDNA inserts were sequenced in high throughput (NIH intramural sequencing center http://www.nisc.nih.gov/)."

ORIGIN

Alignment Scores:

Pred. No.:	3.03e-45	Length:	542
Score:	410.00	Matches:	81
Percent Similarity:	100.00%	Conservative:	0